Attorney Docket No.: 018/258C

geron

GERON CORPORATION
230 Constitution Drive
Menlo Park, CA 94025
Phone: (650) 473-7700
Fax: (650) 473-8654

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Date: November 3, 2003

To: Ann Marie Falk, Ph.D.
U.S. Patent and Trademark Office
Phone: (703) 306-9155
Fax: (703) 872-9306

From: J. Michael Schiff
Director of Intellectual Property
Geron Corporation
Phone: (650) 473-7715
Fax: (650) 473-8654

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Transmittal & Response to Restriction Requirement/Preliminary Amendment for

USSN 09/990,080

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

	Application Number	09/990,080
	Filing Date	November 21, 2001
	First Named Inventor	Gregg B. Morin
	Art Unit	1632
	Examiner Name	Anne Marie Falk
Total Number of Pages in This Submission: 9	Attorney Docket Number	018/258C

ENCLOSURES *(Check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☐ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request (in duplicate)
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
  - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
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- ☐ After Allowance communication to Group
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- ☐ Appeal Communication to Group (Appeal Notice, Brief, Reply Brief) (in duplicate)
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please identify below):

Remarks

1. Response to Restriction Requirement and Preliminary Amendment (7 pages)

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	J. Michael Schiff, Registration No. 40,253
Signature	
Date	MICHAEL SCHIFF Nov 3/03

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Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors: Gregg B. Morin

Filing Date: November 21, 2001

Serial No: 09/990,080

Docket: 018/258c

Title: INACTIVE VARIANTS OF THE HUMAN TELOMERASE CATALYTIC SUBUNIT

Art Unit: 1632

Examiner: Anne Marie Falk, Ph.D.

RESPONSE TO RESTRICTION REQUIREMENT
AND PRELIMINARY AMENDMENT

Commissioner for Patents
Alexandria VA 22313

Dear Sir,

This paper is responsive to the Restriction Requirement mailed on October 3, 2003, for which a shortened statutory period for reply is set to expire on November 3, 2003. Accordingly, this paper is timely filed.

Please enter the following amendments and remarks.

CLAIM AMENDMENTS

1. *(Currently amended)* A protein, peptide, or peptide mimetic that inhibits human telomerase, which either:

   a) has a sequence comprising at least 10 consecutive amino acids ~~encoded by~~ in SEQ. ID NO:2, or encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of a sequence complementary to SEQ. ID NO:1; but which contains one or more deletions consisting essentially of residues 560-565, residues 930-934, or at least 10 consecutive amino acids from residues 323-450, 637-660, 748-766, 1055-1071, or 1084-1116 of SEQ. ID NO:2; or

   b) has a sequence consisting essentially of FFYVTE (SEQ. ID NO:3); FYVT (SEQ. ID NO:5), or at least 10 consecutive amino acids from YGVLLKTHCPLRAA (SEQ. ID NO:4).

2. *(Currently amended)* The protein, peptide, or peptide mimetic of claim 1, which has a sequenc comprising at least 10 consecutive amino acids ~~encoded by~~ in SEQ. ID NO:2, or encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of a sequence complementary to SEQ. ID NO:1; but which contains one or more deletions consisting essentially of residues 560-565, residues 930-934, or at least 10 consecutive amino acids from residues 323-450, 637-660, 748-766, 1055-1071, or 1084-1116 of SEQ. ID NO:2.

3. *(Currently amended)* The protein, peptide, or peptide mimetic of claim 2, which has a sequence comprising at least 25 consecutive amino acids ~~encoded by~~ in SEQ. ID NO:2; but which contains one or more deletions consisting essentially of residues 560-565, 930-934, 323-450, 637-660, 748-766, 1055-1071, or 1084-1116 of SEQ. ID NO:2.

4. *(Original)* The protein, peptide, or peptide mimetic of claim 2, which comprises full-length human telomerase amino acid sequence, except for said deletion(s).

5. *(Original)* The protein, peptide, or peptide mimetic of claim 2, which is a dominant negative mutant.

6. *(Original)* The protein, peptide, or peptide mimetic of claim 5, which binds human telomerase RNA component but lacks processive telomerase activity.

7. *(Original)* The protein, peptide, or peptide mimetic of claim 5, which binds human telomeres but lacks processive telomerase activity.

8. *(Original)* The protein, peptide, or peptide mimetic of claim 1, which has a sequence consisting essentially of FFYVTE (SEQ. ID NO:3); FYVT (SEQ. ID NO:5), or at least 10 consecutive amino acids from YGVLLKTHCPLRAA (SEQ. ID NO:4).

9. *(Original)* The peptide mimetic of claim 8, wherein one or more linkages between consecutive amino acids in the mimetic is $-CH_2NH-$, $-CH_2S-$, $-CH_2CH_2-$, $-CH=CH-$, $-C(=O)CH_2-$, $-CH(OH)CH_2-$, or $-CH_2SO-$.

10. *(Original)* A method of inhibiting telomerase catalytic activity, comprising introducing a protein, peptide, or peptide mimetic according to claim 1 into an environment containing telomerase reverse transcriptase.

11. *(Original)* A method of inhibiting telomerase catalytic activity, comprising introducing into an environment containing telomerase reverse transcriptase and telomerase RNA component a means that inhibits binding of the transcriptase to the RNA component.

12. *(Original)* A method of inhibiting telomerase catalytic activity in a cell, comprising expressing in the cell a nucleic acid encoding a protein or peptide according to claim 2.

13. *(New)* A protein, peptide, or peptide mimetic that is a dominant negative mutant of human telomerase reverse transcriptase having a means for inhibiting telomerase activity.

14. *(New)* The protein, peptide, or peptide mimetic of claim 13, which comprises a means for binding telomerase RNA component, but which lacks telomerase catalytic activity.

15. *(New)* The protein, peptide, or peptide mimetic of claim 13, which lacks a means for binding telomerase RNA component.

16. *(New)* The protein, peptide, or peptide mimetic of claim 14, wherein the telomerase inhibition means comprises at least 10 consecutive amino acids encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of a sequence complementary to SEQ. ID NO:1; but which contains one or more deletions consisting essentially of residues 560-565, residues 930-934, or at least 10 consecutive amino acids from residues 323-450, 637-660, 748-766, 1055-1071, or 1084-1116 of SEQ. ID NO:2.

17. *(New)* The protein, peptide, or peptide mimetic of claim 14, wherein the telomerase inhibition means comprises at least 25 consecutive amino acids in SEQ. ID NO:2, but contains one or more

deletions consisting essentially of residues 560-565, residues 930-934, or at least 10 consecutive amino acids from residues 323-450, 637-660, 748-766, 1055-1071, or 1084-1116.

18. *(New)* The protein, peptide, or peptide mimetic of claim 15, wherein the telomerase inhibition means has a sequence consisting essentially of FFYVTE (SEQ. ID NO:3).

19. *(New)* The protein, peptide, or peptide mimetic of claim 15, wherein the telomerase inhibition means has a sequence consisting essentially of FYVT (SEQ. ID NO:5).

20. *(New)* The protein, peptide, or peptide mimetic of claim 15, wherein the telomerase inhibition means has a sequence consisting essentially of at least 10 consecutive amino acids in YGVLLKTHCPLRAA (SEQ. ID NO:4).

REMARKS

Claims 1-12 were originally presented in this application, and are now subject to a Restriction Requirement under 35 USC § 121. By way of this amendment, claims 13-20 are added, and claims 1-20 are pending.

Amendments

Entry of the claim amendments does not introduce new matter into the disclosure. Support for the new claims may be found at various places in the disclosure: for example, page 4, lines 31-33, page 6 line 40 to page 7 line 2; page 8, line 11 to page 9, line 31; and claims 1-12 as previously presented.

Claims 13-15 express properties of the claimed protein, peptide, or peptide mimetics as a means for inhibiting telomerase activity, and/or a means for binding telomerase RNA component, without the recital of structure, material, or acts in support thereof. This is in accordance with the provisions of 35 USC § 112 ¶ 6.

Election of Group for Examination

Claims 1-12 are subject to a Restriction Requirement under 35 USC § 121 between claims in four groups.

Group I (a protein, peptide, or peptide mimetic having a sequence comprising 10 consecutive amino acids-in SEQ. ID NO:2, or encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of a sequence complementary to SEQ. ID NO:1) is hereby elected for examination on the merits.

Claims 1-7 and 9-12 encompass products in the elected group. New claim 13 is generic to all four groups. New claims 14, 16, and 17 also encompass products in the elected group.

Traverse of Restriction Requirement

Applicant respectfully traverses the restriction requirement.

The Action dated October 3, 2003, indicates that the Office will not examine more than one sequence in an application, because of the continued exponential increase in size of the sequence databases to be searched for each sequence, resulting in a corresponding increase in computer search time and examiner time for reviewing the computer search results.

Applicant sympathizes with the Office that the task of doing full sequence analysis is a substantial task. However, it is not true in this instance that the claims attempt to cover a plurality of unrelated sequences.

Attached to this Amendment is a paper showing that SEQ. ID NOs:3, 4, and 5 are embedded in the human TERT amino acid sequence (SEQ. ID NO:2). Furthermore, SEQ. ID NO:5 is embedded in SEQ. ID NO:3. Accordingly, the Office need only conduct a search and examination with respect to fragments and variants of human TERT (a single species) in order to consider the patentability of the full scope of all the pending claims in this application.

These remarks are not meant to reflect on whether SEQ. ID NOs:1-5 are patentably distinct — only to show that all four groups can be examined together without undue burden on the Office or the Examiner.

Withdrawal of the restriction requirement is respectfully requested.

Request for Rejoinder:

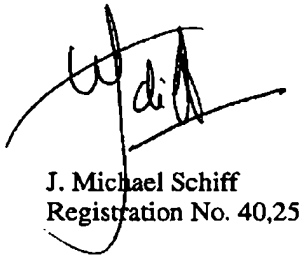
Claim 13 is generic claim that links products in all four groups. In the event that the restriction requirement is maintained, applicant requests that claims in Groups II, III, and IV be rejoined into the group under examination, upon determination that claim 13 is free of prior art.

Conclusion

Applicant respectfully requests that the application proceed to examination on the merits .

In the event the Examiner determines that an interview would facilitate prosecution of this application, she is invited to contact applicant's representative by telephone.

Respectfully submitted,



J. Michael Schiff
Registration No. 40,253

GERON CORPORATION
230 Constitution Drive
Menlo Park, CA 94025
Telephone: (650) 473-7715
Fax: (650) 473-8654

November 3, 2003

APPENDIX

Human Telomerase Reverse Transcriptase
Amino Acid Sequence

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   1  MPRAPRCRAV RSLLRSHYRE VLPLATFVRR LGPQGWRLVQ RGDPAAFRAL VAQCLVCVPW
  61  DARPPPAAPS FRQVSCLKEL VARVLQRLCE RGAKNVLAFG FALLDGARGG PPEAFTTSVR
 121  SYLPNTVTDA LRGSGAWGLL LRRVGDDVLV HLLARCALFV LVAPSCAYQV CGPPLYQLGA
 181  ATQARPPPHA SGPRRRLGCE RAWNHSVREA GVPLGLPAPG ARRRGGSASR SLPLPKRPRR
 241  GAAPEPERTP VGQGSWAHPG RTRGPSDRGF CVVSPARPAE EATSLEGALS GTRHSHPSVG
 301  RQHHAGPPST SRPPRPWDTP CPPVYAETKH FLYSSGDKEQ LRPSFLLSSL RPSLTGARRL
 361  VETIFLGSRP WMPGTPRRLP RLPQRYWQMR PLFLELLGNH AQCP[redacted]VT
 421  PAAGVCAREK PQGSVAAPEE EDTDPRRLVQ LLRQHSSPWQ VYGFVRACLR RLVPPGLWGS
 481  RHNERRFLRN TKKFISLGKH AKLSLQELTW KMSVRDCAWL RRSPGVGCVP AAEHRLREEI
 541  LAKFLHWLMS VYVVELLRS[redacted]TTFQK NRLFFYRKSV WSKLQSIGIR QHLKRVQLRE
 601  LSEAEVRQHR EARPALLTSR LRFIPKPDGL RPIVNMDYVV GARTFRREKR AERLTSRVKA
 661  LFSVLNYERA RRPGLLGASV LGLDDIHRAW RTFVLRVRAQ DPPPELYFVK VDVTGAYDTI
 721  PQDRLTEVIA SIIKPQNTYC VRRYAVVQKA AHGHVRKAFK SHVSTLTDLQ PYMRQFVAHL
 781  QETSPLRDAV VIEQSSSLNE ASSGLFDVFL RFMCHHAVRI RGKSYVQCQG IPQGSILSTL
 841  LCSLCYGDME NKLFAGIRRD GLLLRLVDDF LLVTPHLTHA KTFLRTLVRG VPEYGCVVNL
 901  RKTVVNFPVE DEALGGTAFV QMPAHGLFPW CGLLLDTRTL EVQSDYSSYA RTSIRASLTF
 961  NRGFKAGRNM RRKLFGVLRL KCHSLFLDLQ VNSLQTVCTN IYKILLLQAY RFHACVLQLP
1021  FHQQVWKNPT FFLRVISDTA SLCYSILKAK NAGMSLGAKG AAGPLPSEAV QWLCHQAFLL
1081  KLTRHRVTYV PLLGSLRTAQ TQLSRKLPGT TLTALEAAAN PALPSDFKTI LD
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GERON CORPORATION

230 Constitution Drive
Menlo Park, CA 94025
Telephone: 650 473-7700
Facsimile: 650 473-7750

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